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EXAMINER	
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ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,388	FRAZIER, JEFFERY D.	
	Examiner	Art Unit	
	KAJ K. OLSEN	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-56* is/are pending in the application.

4a) Of the above claim(s) *50-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-49,55,56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/19/04;1/18/05;12/20/06;6/21/07.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 30-49, 55, and 56 in the reply filed on 2/13/2003 is acknowledged. Claims 50-54 are withdrawn from further consideration as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities: Paragraph 0001 should be amended to state that the listed application is now USP 6,726,820.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 46 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2001-188061 (hereafter "JP '061") with evidence from Arai (USP 6,013,168). For JP '061, the examiner is relying on the certified translation provided during the prosecution of application 09/955,608.

5. JP '061 discloses a system comprising a microdevice having a substrate (31, 32), a microscale structures (33, 34) formed in the substrate, and a a rewritable memory 20 integrated

into said substrate which stores information (inherently binary). With respect to the microscale structures being configured to support one or more biomolecule containing samples, Arai evidences that electrophoretic devices like JP '061 are inherently capable of supporting biomolecules because electrophoresis is typically performed on either proteins or nucleic acids. See col. 1, ll. 13-15.

6. With respect to the use of a detector, see paragraphs 0003 and 0015 of JP '061

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 30-33, 38-41, 49, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of Arai and either Zanzucchi et al (USP 5,585,069) or Kercso et al (USP 6,132,685).

9. JP '061 discloses a system comprising a microdevice having a substrate (31, 32), a separation channel 33 formed in the substrate, a rewritable memory 20 integrated into said substrate which stores information (inherently binary). JP '061 further discloses a means for causing at least one or analytes to migrate along the separation channel thereby separating said analyte. See fig. 1 and 2 and paragraphs 0003 and 0010. JP '061 does not explicitly disclose storing information about the analyte onto the chip nor does JP '061 explicitly identify biomolecules as being the analyte for the system. Arai establishes that the typical analyte for an

electrophoretic experiment are biomolecules such as proteins and nucleic acids. See col. 1, ll. 13-15. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the system of JP '061 for biomolecules, as suggested by Arai, because biomolecules are a typical analyte for electrophoretic systems. With respect to storing information about the biomolecules onto the memory, Zanzucchi suggests that information about the sample being analyzed by a microfluidic device should be included on the microfluidic device itself in the form of a barcode or other high density code. See col. 5, l. 59 - col. 6, l. 2. Kercso similarly teaches that information pertaining to the sample itself should be included on a plate holding a sample to facilitate sample management, and further suggests similar sample management can be utilized throughout all stages of the device, which includes microfluidic analysis. See fig. 5A and col. 8, ll. 24-38. Because both Zanzucchi and Kercso suggests that information about the sample constituent should be included with the microfluidic analysis for sample management purposes, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the memory of JP '061 to also contain information about the sample constituent so that the sample being analyzed by the microfluidic device is also suitably archived for sample management purposes. JP '061 even suggested that the contents of the included memory is not limited to the explicit examples given by JP '061. See paragraph 0012. Because Arai already identified biomolecules as being a suitable analyte for JP '061, information about the biomolecular containing sample (see Zanzucchi and Kercso) would read on the defined "character…of one of more biomolecules" giving the claim language its broadest reasonable interpretation.

10. With respect to the substrate composition and the use of an electric field, see paragraph 0003 of JP '061.

11. With respect to the memory being permanently affixed to the substrate, because JP '012 does not suggest removing the memory from the device and because one of the purposes of the memory is keep track of the use of the microfluidic device (paragraph 0012), one possessing ordinary skill in the art would recognize that the memory could be permanently affixed to the substrate such that it cannot be inadvertently removed thereby losing the history of the particular microfluidic device.

12. With respect to the type of memory, the EEPROM relied on by JP '061 would appear to read on either integrated circuit or thin film semiconductor memory. With respect to the amount of memory, finding the amount of memory that provides all the necessary storage capacity for the data to be stored, including the use of one megabyte, requires only routine skill in the art.

13. With respect to the use of a detector, see paragraphs 0003 and 0015 of JP '061

14. With respect to claim 49 (those limitations not discussed above), because the memory of JP '061 is meant to interface multiple analyzers (see paragraph 0013), it would have been obvious to one of ordinary skill in the art to place the machine-readable code necessary for reading or writing all of the data to the memory in the event that one of the analyzers utilized either does not have the appropriate code or does not have an updated version of the code. Placing this code on the memory itself would prevent different analyzers from accessing or transmitting data differently (or failing to do either).

15. With respect to claim 55 (those limitations not discussed above), storing information about the sample itself onto the memory (as rendered obvious by Zanzucchi and Kerso) would make the memory of JP '061 utilized for such a function a sample tracking device.

16. Claims 30-33, 38-41, 49, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of either Fujimiya et al (USP 6,017,434) or Simpson et al (USP 6,017,434).

17. JP '061 discloses a system comprising a microdevice having a substrate (31, 32), a separation channel 33 formed in the substrate, a rewritable memory 20 integrated into said substrate which stores information (inherently binary). JP '061 further discloses a means for causing at least one or analytes to migrate along the separation channel thereby separating said analyte. See fig. 1 and 2 and paragraphs 0003 and 0010. JP '061 does not explicitly disclose storing information about the analyte onto the chip nor does JP '061 explicitly identify biomolecules as being the analyte for the system. However, Fujimiya teaches that a sample typically being analyzed by electrophoresis is DNA (a biomolecule) and further teaches that he measured sequencing data from the electrophoretic experiment should be stored on a data storage means for future reference. See col. 22, ll. 1-13. Simpson also teaches that electrophoresis is typically utilized for biomolecular analytes like DNA and also teaches that the measured sequence data for the DNA should be stored on a data storage means for future access and/or analysis. See col. 8, ll. 13-26. Because it was known that sequencing information from an electrophoretic experiment are typically stored in some memory means and because JP '061 was open ended about what information could be stored on the memory means (see "and so forth may be mentioned as information stored in EEPROM 20" in paragraph 0012), one possessing

ordinary skill in the art would recognize that the memory of JP '061 could also store the measured sequence of the one or more biomolecules from the electrophoretic experiment, as suggested by Fujimiya and Simpson, to increase the utility of the already present memory means.

18. With respect to the various dependent claims, see the discussion of JP '061 in the preceding rejection.

19. With respect to claim 49 (those limitations not discussed above), because the memory of JP '061 is meant to interface multiple analyzers (see paragraph 0013), it would have been obvious to one of ordinary skill in the art to place the machine-readable code necessary for reading or writing all of the data to the memory in the event that one of the analyzers utilized either does not have the appropriate code or does not have an updated version of the code. Placing this code on the memory itself would prevent different analyzers from accessing or transmitting data differently (or failing to do either).

20. With respect to claim 55 (those limitations not discussed above), storing information about the sample itself onto the memory (as rendered obvious by Fujimiya and Simpson) would make the memory of JP '061 utilized for such a function a sample tracking device.

21. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of Arai and Zanzucchi or Kercso, or JP '061 in view of either Fujimiya or Simpson as applied to claim 30 above, and further in view of either Bjornson et al (USP 6,103,199) or Parce et al (USP 6,458,259) with or without the further teaching of Kroy et al (USP 5,252,294).

22. The references set forth all the limitations of claim 34, but did not explicitly recite that the means for causing the biomolecules to migrate comprised centrifugal force. However, both Bjornson and Parce teach that centrifugal forces are a conventional alternative to the use of

electrosmotic and electrophoretic flow means for microchip devices. See Bjornson, col. 11, l. 55 - col. 12, l. 5 and Parce, col. 7, l. 63 - col. 8, l. 9. Because Bjornson and Parce demonstrate that centrifugal force means are conventional in microfluidic device art, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of centrifugal forces for the force means of JP '061 because the substitution of one known force for another requires only routine skill in the art.

23. With respect to claim 35, the use of centrifugal force inherently requires that the device be a spinning-disc. See for example Parce, col. 7, ll. 63-63-67.

24. With respect to claim 36, JP '061 does not explicitly suggest the use of optical memory as the storage means. However, Kroy teaches that optical memory was already a well known means for storing measurement data. See col. 5, ll. 45-59. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of optical memory, as suggested by Kroy, for the memory means of JP '061 because the substitution of one known memory means for another requires only routine skill in the art.

25. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of Arai and Zanzucchi or Kercso, or JP '061 in view of either Fujimiya or Simpson as applied to claim 30 above, and further in view of Bjornson.

26. The references set forth all the limitations of the claims, but did not explicitly disclose the presence of a plurality of non-intersecting separation channels. Bjornson teaches that it is conventional in the microfluidic art to include multiple non-intersecting separation channels on a single microchip so as to increase the amount of analysis that can be done with a single device. See fig. 5-7 and col. 8, ll. 13-40. It would have been obvious to one of ordinary skill in the art at

the time the invention was being made to utilize the teaching of Bjornson for the system of JP '061 in view of Arai and Zanzucchi or Kercso, or JP '061 in view of either Fujimiya or Simpson in order to increase the amount of analysis that can be done with a single device.

27. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of Arai and Zanzucchi or Kercso, or JP '061 in view of either Fujimiya or Simpson as applied to claim 30 above, and further in view of Kaltenbach et al (USP 5,641,400).

28. The references set forth all the limitations of the claim, but did not explicitly recite the presence of a temperature control device to modulate the temperature of the substrate. Kaltenbach teaches that microfluidic separation techniques can be affected by temperature and teaches the use of a temperature control device to regulate said temperature. See col. 3, ll. 9-38. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kaltenbach for the system of JP '061 in view of Arai and Zanzucchi or Kercso, or JP '061 in view of either Fujimiya or Simpson in order to ensure that the temperature variation does not affect the quality of the separation being performed.

29. Claims 43-45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of Arai, either Zanzucchi and/or Kercso, and Kaltenbach.

30. JP '061 discloses a system comprising a microdevice having a substrate (31, 32), a rewritable memory 20 integrated into said substrate which stores information (inherently binary). See fig. 1 and 2 and paragraphs 0003 and 0010. JP '061 does not explicitly disclose storing information about the analyte onto the chip, the use of an array of polynucleotides as being the analyte for the system, or the use of a temperature control device. Arai establishes that the typical analyte for an electrophoretic experiment are biomolecules such as nucleic acids (i.e.

polynucleotides). See col. 1, ll. 13-15. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the system of JP '061 for polynucleotides, as suggested by Arai, because polynucleotides are a typical analyte for electrophoretic systems. With respect to storing information about the biomolecules onto the memory, Zanzucchi suggests that information about the sample being analyzed by a microfluidic device should be included on the microfluidic device itself in the form of a barcode or other high density code. See col. 5, l. 59 - col. 6, l. 2. Kercso similarly teaches that information pertaining to the sample itself should be included on a plate holding a sample to facilitate sample management, and further suggests similar sample management can be utilized throughout all stages of the device, which includes microfluidic analysis. See fig. 5A and col. 8, ll. 24-38. Because both Zanzucchi and Kercso suggests that information about the sample constituent should be included with the microfluidic analysis for sample management purposes, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the memory of JP '061 to also contain information about the sample constituent so that the sample being analyzed by the microfluidic device is also suitably archived for sample management purposes. JP '061 even suggested that the contents of the included memory is not limited to the explicit examples given by JP '061. See paragraph 0012. Because Arai already identified biomolecules as being a suitable analyte for JP '061, information about the biomolecular containing sample (see Zanzucchi and Kercso) would read on the defined "character…of one of more biomolecules" giving the claim language its broadest reasonable interpretation. With respect to the temperature control, Kaltenbach teaches that microfluidic separation techniques can be affected by temperature and teaches the use of a temperature

control device to regulate said temperature. See col. 3, ll. 9-38. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kaltenbach for the system of JP '061 in view of Arai and Zanzucchi or Kercso, in order to ensure that the temperature variation do not affect the quality of the separation being performed.

31. With respect to the use of optical communication, see paragraph 0014 of JP '061.

32. With respect to claim 56 (those limitations not discussed above), storing information about the sample itself onto the memory (as rendered obvious by Zanzucchi and Kerso) would make the memory of JP '061 utilized for such a function a sample tracking device.

33. Claims 43-45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of either Fujimiya or Simpson, and Kaltenbach.

34. JP '061 discloses a system comprising a microdevice having a substrate (31, 32), a rewritable memory 20 integrated into said substrate which stores information (inherently binary). See fig. 1 and 2 and paragraphs 0003 and 0010. JP '061 does not explicitly disclose storing information about the analyte onto the chip, identify polynucleotides as being the analyte for the system, or disclose the use of a temperature control device. However, Fujimiya teaches that a sample typically being analyzed by electrophoresis is DNA (a polynucleotide) and further teaches that the measured sequencing data from the electrophoretic experiment should be stored on a data storage means for future reference. See col. 22, ll. 1-13. Simpson also teaches that electrophoresis is typically utilized for polynucleotides analytes like DNA and also teaches that the measured sequence data for the DNA should be stored on a data storage means for future access and/or analysis. See col. 8, ll. 13-26. Because it was known that sequencing information from an electrophoretic experiment are typically stored in some memory means and because JP

'061 was open ended about what information could be stored on the memory means (see "and so forth may be mentioned as information stored in EEPROM 20" in paragraph 0012), one possessing ordinary skill in the art would recognize that the memory of JP '061 could also store the measured sequence of the one or more biomolecules from the electrophoretic experiment, as suggested by Fujimiya and Simpson, to increase the utility of the already present memory means. With respect to the temperature control, Kaltenbach teaches that microfluidic separation techniques can be affected by temperature and teaches the use of a temperature control device to regulate said temperature. See col. 3, ll. 9-38. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kaltenbach for the system of JP '061 in view of Fujimiya or Simpson, in order to ensure that the temperature variation do not affect the quality of the separation being performed.

35. With respect to the use of optical communication, see paragraph 0014 of JP '061.

36. With respect to claim 56 (those limitations not discussed above), storing information about the sample itself onto the memory (as rendered obvious by Fujimiya or Simpson) would make the memory of JP '061 utilized for such a function a sample tracking device.

37. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '061 in view of Kaltenbach.

38. JP '061 set forth all the limitations of the claim, but did not explicitly recite the presence of a temperature control device to modulate the temperature of the substrate. Kaltenbach teaches that microfluidic separation techniques can be affected by temperature and teaches the use of a temperature control device to regulate said temperature. See col. 3, ll. 9-38. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the

teaching of Kaltenbach for the system of JP '061 in order to ensure that the temperature variation do not affect the quality of the separation being performed.

Double Patenting

39. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

40. Claims 30-49, 55, and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 28 of copending Application No. 10/959,746 with or without the further teaching of JP '061. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant invention sets forth all the limitations of claim 1-15 of application '746, but independent claims 30, 49, and 55 of the instant invention explicitly identify the use of a "separation channel" over the more generic "channel" of claim 1 of application '746. However, JP '061 already set forth that channels placed on microfluidic devices find utility as separation

channels. See the rejection above. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the channel disclosed by application '746 as a separation channel as set forth by JP '061 because separations are a conventional means for analyzing the sample of interest. With respect to independent claims 43 and 54 of the instant invention and the array of polynucleotides, claim 14 of application '746 already set forth that the analysis could be for polynucleotides. With respect to independent claim 46 and the microscale structure, claim 2 of application '746 already set forth that the device could have structures on the order of 750 microns. With respect to the machine readable code of independent claim 49 of the instant invention, see claim 28 of application '746. With respect to the sample tracking device of claims 55 and 56 of the instant invention, storing information about the character or sequence of the biomolecules in the device inherently constitutes a sample tracking device giving the claim language its broadest reasonable interpretation.

41. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
May 27, 2008